DETAILED ACTION

Summary

Receipt of Applicant's Response and Claim amendments filed on 07/08/11 is also acknowledged. Claims 1, 5-6, 8-9, 11-22, 24, 27-43 are pending and claims 6, 11-14, 24, and 27-42 remain withdrawn. Claims 1, 5, 8-9, 15-22 and 43 are rejected.

It is noted that the action mailed on 08/31/11 inadvertently left out the "conclusion" section with the paragraph about finality and as such this action is being issued to replace that.

MAINTAINED REJECTIONS

DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 8-9, 15-22, and 43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 7,329,418. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to an immediate release pharmaceutical tablet with at least two segments, said tablet containing a drug or drugs, in which: (a) said tablet includes two or more segments and all segments that contain a pharmacologically effective dose of a drug or drug contain the same drug (or combination of drugs at the same ratio).

Claims 1, 5, and 16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-6 and 8 of U.S. Patent No. 7,622,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to an immediate release pharmaceutical tablet with at least two segments, said tablet containing a drug or drugs, in which: (a) said tablet includes two or more segments and all segments that contain a pharmacologically effective dose of a drug or drug contain the same drug (or combination of drugs at the same ratio).

Response to Arguments

The ODP rejections over US 7,329,418 and 7,622,137 are maintained, however it is acknowledged that Applicants have agreed to submit Terminal disclaimers to

obviate the ODP rejections upon indication of allowable subject matter in the instant application.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain support for one inactive segment "one or more excipients known for use in immediate release pharmaceutical formulations" or at least two active segments of "excipients known for use in immediate release pharmaceutical formulations" as claimed in instant claim 1. While the instant specification does teach an 'inactive segment' [0076, 0080, 0108, 0101, 0121, 0125-0126, etc.] and specific ingredients in the active segments [0081-0102], nowhere is "one or more excipients known for use in immediate release pharmaceutical formulations" disclosed. This is a new matter rejection.

MAINTAINED-Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 8-9, 15-22, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/18447 in view of EP 0348683 and Pharmaceutical Industry Info (2003) and further in view of US 5,118,021 ('021) and US 4,905,589 ('589).

The instant claims are drawn to an immediate release pharmaceutical tablet with at least three segments, said tablet containing a dose of drug or drugs, in which: said tablet includes at least one inactive segment consisting of one or more excipients known for use in immediate release formulations, said inactive segment being adapted to be broken for dividing the dose prior to administration and at least two active segments each consisting of excipients known for use in immediate release pharmaceutical formulations and a pharmacologically effective dose of the same drug or combination of drugs, wherein the three-segment tablet has a height greater than its width in the tablet die and the inactive segment is disposed between the two active segments and has a height greater than the combined height of the active layers.

- '447 teaches a multiplex drug delivery system containing two distinct drug dosage packages with equivalent dissolution profiles and/or identical composition for the active provided in an effective amount that is scored and that the drug dosage packages are immediate release form (abstract, pg. 1 lines 8-10; pg. 3,

lines 1-5; Fig. 1). According to '447 the same active in the same amount with the same dissolution, that is scored or marked and that the inactive layer is greater in height wherein the immediate release compartment is 3/16 diameter round whereas the scored compartment is 5/16x3/4 (abstract, pg. 1 lines 8-10; pg. 3, lines 1-5; Fig. 1; pg. 9, Example), such that the inactive component height of ¾ is greater than the height of both actives (i.e. 6/16) (meeting the limitations of claim 1, 5, 8-9, 17, 19-20 and 22).

- Various drugs are taught for the tablet of '447 with are known to treat arthritis, pain, cardiac diseases, etc. (pg. 7, lines 5-pg. 8, lines 20) (according to the limitations of claim 43).
- '447 does not teach that the active and inactive components are layered, a height greater than its width in the tablet die, or an "immediate release" inactive component.
- '683 teaches an immediate release multi-layered tablet wherein the active layers are interspersed with layers containing conventional pharmaceutical excipients such as microcrystalline cellulose (abstract, pg. 4, lines 12-16). Pharmaceutical Industry Info (2003) teaches that the KORSCH TRP 700/900 (tablet press) forms tri-layer and five-layer tablets that have deep filling depths (pg. 2) (see cited as interest for a visual of the KORSCH TRP 700/900 tablet press, which shows "a height greater than its width in the tablet die") (according to the limitations of claims 1 and 10).

- '447, '683 and Pharmaceutical Industry Info (2002) do not teach colored or printed indicia of instant claims 18 and 20-22.
- '021 discloses that dosage forms, such as tablets, can be marked or scored for splitting and that reasons for reasons for splitting tablets include difficulty of swallowing tablets in whole form and dosage in standard tablet is greater than required (column 1, lines 11-44). '589 discloses that an ink-jet apparatus for marking tablets with appropriate indicia (abstract) (according to the limitations of instant claims 18 and 20-22).
- Note the limitation "known for use in immediate release pharmaceutical formulations" of instant claim 1 is not further limiting to instant claimed "one or more excipients" as it is intended use of the excipients.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '447, '683 and Pharmaceutical Industry Info (2002) with '021 or '589. A skilled artisan would know how to substitute the inactive layer of '683 (i.e. microcrystalline cellulose) into the composition of '447 with predictable results. Such a simple substitution of inactive layer for another is within the purview of the skilled artisan and would yield predictable results of an immediate release dosage form. Further a skilled artisan desiring to make the known product (immediate release active components separated by an inactive component) of '447 ready for improvement, with the known technique of formulating multilayered tablet of '683 and Pharmaceutical Industry Info wherein the deep fill depths of the KORSCH TCP 700/900 allow for a taller than wide 3 and 5 layered dosage form with predictable results of an immediate release

dosage form with 3 or 5 layers wherein the active layers are separated by microcrystalline cellulose. Combination of a known product (substantially identical drug components separated by an inactive component) and a known technique of formulating a multilayered/segmented taller than wide tablet is within the purview of the skilled artisan and would yield predictable results of an immediate release dosage form with 3 or 5 layers wherein the active layers are separated by microcrystalline cellulose. A skilled artisan desiring to make the known product (i.e. multilayered tablet) of '447, '683 and Pharmaceutical Industry Info ready for improvement, with the known technique of formulating a product which contains a mark such as colored/printed indicia of '021 and '589 with predictable results. The combination of a known scored multilayered product '447, '683 and Pharmaceutical Industry Info ready for improvement with a known technique of marking '021 and '589 is within the purview of the skilled artisan and would yield predictable results.

Cited As Interest

KORSCH TRP 700/900 it is noted that according to the product guide on KORSCH's website the "KORSCH TRP 700/900" makes multilayered tablets that have a height greater than width in the tablet die and the middle segment can be taller than the other 2 segments and shows each segment a different color with visible marks inbetween segments (see pages 3 and 5).

US 2005/0169991 ('991) teaches that the "immediate release excipients" are the same immediate release portions and sustained release portions of their tablet and

rather it is the amount used that determines whether a layer is sustained release or immediate release and '991 teaches common inert diluents and fillers include microcrystalline cellulose, sucrose, starches, etc. [0082, 0129-0130].

Response to Arguments

Applicant's arguments with respect to the instant claims have been considered but are not persuasive and are further moot in view of the new grounds of rejection necessitated by applicants' amendments. It is noted that the claim amendments overcame the 103 rejections over '608 in view of '104 and '447 and '608 in view of '104 and '447 and further in view of '021 and '589 as they do not teach "a height greater than its width in the tablet die". Further, the newly added limitation "known for use in immediate release pharmaceutical formulations" of instant claim 1 is not further limiting to instant claimed "one or more excipients" as it is intended use of the excipients and in view of the cited as interest '991 the excipients are the same immediate release portions and sustained release portions of a tablet and rather it is the amount used that determines whether a layer is sustained release or immediate release and '991 teaches common inert diluents and fillers include microcrystalline cellulose, sucrose, starches, etc. [0082, 0129-0130].

Applicant states that the prior art does not teach a "tablet which provides the specific advantages achieved by the claimed tablet configuration" and the points out these advantages on pages 17-18 of the response. The Examiner encourages the Applicant to supply a declaration or factual evidence on the record to show the

advantages of the instant tablet compared to the prior art. Such a declaration would distinguish the instant invention and overcome the obviousness rejection of record.

Applicant argues that '447 does not teach "an IR inactive component" or "suggest that the tablet (the final dosage form) is formed in a taller-than-wide….as measured in the tablet die". Applicant argues that the "limitations of the press coating process" of '447 cannot form a "taller-than-wide" tablet and that '683 describes "three layer tablet having an inactive layer for separating incompatible actives in the other two layers…[and] fails to describe a tablet that is taller-than-wide" and that there is no taller than wide configuration in '683 or Pharmaceutical Industry Info. Applicant argues that "other than impermissible use of applicants' own disclosure as a basis for hindsight reconstruction of the claimed invention, the motivation to combine the these two cited references and their combined teaching or suggestion of the claimed invention appear to be absent". The Examiner respectfully points out that the remaining rejection is a combination 103 rejection and Applicant's argue against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

It should be noted that the motivation to combine references can be different from the ones set forth by Applicant. That is, as long as motivation exists to combine the elements, the problem to be solved does not have to involve the same reason for making the inert component out of microcrystalline cellulose. As such, the

examiner respectfully submits that there is motivation to combine the teachings of '447 in view of '683 and Pharmaceutical Industry Info and further in view of '021 and '589 and the expected result of an immediate release tablet that is taller-than-wide….as measured in the tablet die with an inert segment comprised of filler such a microcrystalline cellulose that is greater in height than the combined 2 immediate release active cores and further serves to separate 2 immediate release active cores. Under KSR teaching, suggestion and motivation (TSM) is but one rationale (See MPEP 2141), many other rationale exist and the Examiner has not relied upon TSM but i) the simple substitution of one excipient for another and ii) the combination of known product ready for improvement with known techniques for a similar purpose (i.e. tableting). Such a combination of known tableting excipients (i.e. microcrystalline cellulose) and known tableting machines (i.e. KORSCH TCP 700/900) to formulate a known scored multi-segmented dosage form of the prior art is within the purview of the skilled artisan and would yield predictable results of a 3 or 5 layered scored tablet with immediate release active segments separated by inert microcrystalline segments wherein the tablets are taller than wide. As stated above a skilled artisan would know how to substitute the inactive layer of '683 (i.e. microcrystalline cellulose) into the composition of '447 with predictable results of an immediate release dosage form. Further a skilled artisan desiring to make the known product (immediate release active components separated by an inactive component) of '447 ready for improvement, with the known technique of formulating multilayered tablet of '683 and Pharmaceutical Industry Info wherein the deep fill depths of the KORSCH TCP 700/900 allow for a taller than wide 3 and 5

layered dosage form with predictable results of an immediate release dosage form with 3 or 5 layers wherein the active layers are separated by microcrystalline cellulose. A skilled artisan desiring to make the known product (i.e. multilayered tablet) of '447, '683 and Pharmaceutical Industry Info ready for improvement, with the known technique of formulating a product which contains a mark such as colored/printed indicia of '021 and '589 with predictable results. Applicant has not shown via factual evidence on the record what is unexpected or not predictable about the instant invention and currently it appears to be commonly known and practiced in the tableting art as cited in the rejection of record '447, '683, Pharmaceutical Industry Info, '021 and '589.

Applicant argues that the KORSCH TRP 700/900 is "accepted in the art as useful for manufacturing controlled-release (CR) tablets…having an expandable "push layer" which enabled the release of a drug to be modified", etc. The Examiner respectfully requests a citation for these remarks as a reading of page 2 of Pharmaceutical Industry Info (2003) as cited by the Examiner says nothing about CR tablets or push layers. Applicant goes on to state that it would be "difficult if not impossible to break through the tablets made in accordance with the known process using the Korsch multilayer tablet press…breaking through an inactive push layer of the prior art "controlled release" tablets can render such tablets inoperable". The Examiner respectfully points out that these statements appear to be opinion or hearsay as the Applicant has not supplied a citation or factual evidence of record in the form of a declaration to support this.

Conclusions

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)272-6175. The examiner can normally be reached on M-F, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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